1	UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY
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3	IN RE: VALSARTAN, LOSARTAN, CIVIL ACTION NUMBER:
4	and IRBESARTAN PRODUCTS 1:19-md-02875-RMB-SAK
5	LIABILITY LITIGATION Deposition Designations
6	via TEAMS videoconference
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8	Mitchell H. Cohen Building & U.S. Courthouse 4th and Cooper Streets Camden, New Jersey 08101 Tuesday, October 8, 2024 Commencing at 1:00 p.m.
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11	B E F O R E: THE HONORABLE THOMAS I. VANASKIE (RET.) SPECIAL MASTER
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(PROCEEDINGS held via remote TEAMS videoconferencing before the Honorable Thomas I. Vanaskie (Ret.), Special Master, at 1:00 p.m. as follows:)

THE COURT: Are you able to hear me?

Good afternoon. And are we ready to proceed with discussions on deposition designations for Teva-related witnesses?

MR. STANOCH: Yes, Judge.

THE COURT: All right. Now, I have the designations and counterdesignations and objections on the spreadsheet for Mr. Binsol.

Where do things stand with respect to Mr. Nudelman?

MS. LOCKARD: So, Your Honor, at the last hearing you had asked that we go ahead and provide Mr. Binsol — or excuse me, Mr. Nudelman and Mr. Barreto to plaintiffs' counsel, even though we had a reservation about that because we felt like we needed Judge Bumb's ruling on the "general cause" issues, and also because there was an outstanding dispute about whether plaintiffs could play designations of Mr. Barreto if he was being called live. And Your Honor instructed us to go ahead and provide those. So I did provide Nudelman's. We're finalizing Barreto's today. And I plan to get that over to plaintiffs' counsel.

But from my perspective, Nudelman is ready for Your Honor. But I believe Mr. Stanoch had sent an email that said

we should wait until Judge Bumb rules, which was our initial position.

MR. STANOCH: I was just summarizing Ms. Lockard's position, Your Honor. I don't think we should wait, but I was just being fair in an email to Your Honor to convey what I thought Ms. Lockard said. And it sounds like I was right.

(Laughter.)

THE COURT: Well, I understood your email, David, to be suggesting that we defer Mr. Nudelman until after Thursday; and I'm inclined to do that. I'm sorry for that, Victoria, because of all the effort that was put in to get those designations to me. But I am inclined to defer until after Thursday.

But we are prepared to address Mr. Binsol today. And Mr. Barreto is in a different category.

MS. LOCKARD: Right. Mr. Barreto is in a different category. But we're going to get those because Your Honor instructed us to, and we're fine to do that. It's just he's got — even though counsel has cut down the designations significantly, I see that now as I'm going through them, but it is two days of deposition, so it was a rather long deposition. And I think there are, you know, over 200 rows that were originally designated that have been revised.

So even though counsel has cut those down, I still have to go through and see what was taken out and is it

something that we are missing a counter to and so forth. So it's just taking a little bit of time. But I'm committed to getting that over to Mr. Stanoch, you know, this evening, you know, after today, after this evening.

THE COURT: All right. And is it all right to defer Mr. Nudelman until after Thursday?

MS. LOCKARD: No objection to that. I thought we should do that -- I think it would probably be more efficient for everybody if we do that, so...

THE COURT: Okay. That's what we're going to do then.

So the only witness we'll address today is Mr. Binsol. All right.

MR. STANOCH: Yes, sir.

THE COURT: And I've had the first dispute with respect to Mr. Binsol appearing on page 41 of his deposition.

MS. LOCKARD: So the first -- I had a question mark just on the initial designation on page 23, Judge. And the issue that I just wanted to raise is, you know, in prior designations, we had initially designated or counterdesignated background information for these witnesses to provide their role and some basic educational information and plaintiffs cut that. They didn't want to play the educational information or even in some instances the role or the title of the witness at Teva, and they've been saying, well, we can just announce who

this witness is and what their role is and we don't need their educational background.

But in this witness's instance --

THE COURT: Right.

MS. LOCKARD: -- they take a different position. And my only conclusion can be because Mr. Binsol went to community college and got an online degree. And I think it's a bit prejudicial if they want to play his educational information but they don't want to let us play as a counter the educational background of our other witnesses who have Ph.D.s from notable universities.

So I don't have a strong legal objection to this, but I just think it's a little bit inconsistent and unfair.

THE COURT: All right. David.

MR. STANOCH: Your Honor, if there's no formal legal objection, then I don't think there's a dispute, and I don't have a legal argument I need to make back.

I am designating -- we're designating here testimony about a Teva witness. It's nothing about this designation that there is anything objectionable.

In fact, you know, like Ms. Lockard said, in the context of other objections, they are putting in affirmatives and counters we have seen for three weeks about background and positions they held. So I don't think there's any issue for you to decide here. If there's no formal objection is what I

heard, then I think the testimony comes in. I mean, especially it's certainly, you know, relevant and probative about the witness and his 30(b)(6) and 30(b)(1) capacity. So I'm not sure what more I need to say, Your Honor.

MS. LOCKARD: Well, I said I don't --

THE COURT: Well, I am a little bit concerned about highlighting the fact that he's got a community college degree and then online degree after that. It just does strike me as somewhat strange that you designated his educational background but not the educational background of other witnesses.

MR. STANOCH: I'm still not sure, Your Honor, even with that about what the objection -- the legal objection is to the admissibility of this testimony.

It's certainly probative of this witness who unlike all of the other witnesses, Your Honor, we've heard for weeks that he will be talking about quality issues and we'll have someone from Teva about quality, this is the person, and we will see, talking about testing, knowledge, information of NDMA, et cetera, et cetera. So his background certainly is probative and relevant. So I don't think there's an issue with that.

And, you know, if he was on the stand, if he was live, obviously we could or could not call him for that. And Teva has designated affirmatives or counters for the other witnesses we've seen to this point on this. So, again, I don't

understand what legal objection or basis there would be to preclude this testimony.

And, frankly, I'm being honest, I still haven't heard other than they don't like potentially an inference a jury may draw that their quality designee has an Associate's degree and then a liberal arts background in French business, not in cGMP or biochemical pharmaceutical testing, but that's argument, and the jury can hear that information and take from it what they will or will not.

THE COURT: All right. Victoria.

MS. LOCKARD: Well, we did not — we had initially counterdesignated our other witnesses' educational background and plaintiffs objected to that. This is before, Judge Vanaskie, before you saw, this was back in the negotiation stage. And we took out our counters for the other witnesses on the education piece. And we did propose counters for their title or their role, which Your Honor looked at.

But we took out all of our counters that had their educational background, because, you know, in fairness, plaintiffs said, well, it's their testimony and if they didn't want to play the educational background, we could play it in our affirmatives.

But here, I mean, I said I didn't have a strong legal objection, I do have a prejudice objection, and I do have a 611(a) objection, because I do think this is somewhat intended

just to embarrass and harass the witness about the strength of his educational background.

And, again, the reason I am putting it the way I am is because if they had put in educational background on all the other witnesses, then certainly I wouldn't object to this.

It's the truth. And, you know, if educational background is relevant to one witness, then it's relevant to all I guess would be my position. And if they're saying it's not relevant to the others, then why suddenly is it now relevant to this witness?

THE COURT: Go ahead, David.

MR. STANOCH: Your Honor, I don't want to belabor this. We are permitted to put in the designations and play the party opponent testimony we would like as we choose. I don't understand how it's prejudicial to disclose a witness's educational background. I'm now hearing it's a prejudice objection so we're in the 403 world. I do not see how it's unduly prejudicial.

Teva hired this person. He worked at Teva for a number of years and now Teva's not prepared to let a jury know what qualifications their employees do or do not have. I disagree that that's unduly prejudicial.

And what might have been done for some other witness or the other, I don't have in front of me, and this issue wasn't raised before. And if they want to counterdesignate or

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affirmatively designate, they can argue for something else about this witness or any other witness which they had dealt with before. They've had these designations since February, as they did with all the other witnesses. This is not -- no surprise here. We're not trying to pull a fast-one. THE COURT: Yeah. I understand your concern, Victoria, but I have to say that this is proper examination of a witness. Background is important in some instances. In some instances, it isn't. I can't speak for what you withdrew at the request of the plaintiff with respect to other witnesses. I know there's a lot of time pressure on counsel and so that might have influenced what was withdrawn. But I don't have a basis to grant this objection. Its prejudicial nature does not substantially outweigh its probative value. All right. MS. LOCKARD: Understood. I won't -- I won't say anything more on that one. THE COURT: All right. And now do we go to page --MS. LOCKARD: I think 41. THE COURT: That's what I had, 41. MS. LOCKARD: And it looks like plaintiffs withdrew everything except line 5 to 6 on page 41. So we are agreeable

> United States District Court District of New Jersey

THE COURT: All right. So nothing to decide with

to that. We can keep in the answer.

respect to row 4 of the spreadsheet.

MR. STANOCH: Agreed.

THE COURT: I think that takes us to row 5 of the spreadsheet.

MR. STANOCH: Right.

MS. LOCKARD: Right. So row 5 we objected to this based on relevance, prejudice, misleading, and in addition,
Judge Bumb had ruled on MIL 11 which relates to Teva's API
suppliers other than ZHP. And this really gets into the whole piece of the case involving Mylan, and the Mylan API was used at Teva's Jerusalem facility.

Remember the ZHP API was used at Teva's Malta facility, which we do agree is relevant. But this line of questioning goes to the Mylan product being used in the Jerusalem facility, why that facility closed. And, you know, as Judge Bumb said in her comments, that this is really taking us down a path where we don't need to be.

THE COURT: All right. David.

MR. STANOCH: Your Honor, and this -- I'm going to step back for just two seconds to give some background because I think it will apply to some other questioning here.

We're not trying to prove anything with -- about Mylan's API.

Three and a half years ago when I deposed Mr. Binsol, I had to depose him as a 30(b)(6) and 30(b)(1) on Teva's use of both ZHP and Mylan API because they were buying both at the

same time.

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This document I have in front of him, right, while it's a Teva business record, and I use it, and you'll see in the questions, use it to go through principles about NDMA, NDMA formation, the ICH M7 guidelines that Teva put in its own document, in its own business record.

Now, the fact that the document initially might have been about Mylan I think is not the point and should not be determinative here, because I'm not using anything here to prove anything about Mylan or open the door to Mylan or waste the jury's time on Mylan API at all. But this goes to knowledge, information of NDMA and the feasibility of knowing how NDMA is formed, as Teva writes generically in this document, right, about NDMA, and nothing really about NDEA and Mylan, right?

If there's something specific here in this designation or in an ensuing one, I'm happy to find a way to potentially scrub out the word "Mylan." I don't think there's a reference of Mylan in this answer.

I think the question and answer that's designated focuses on general information that was in the record that was talking about NDMA. That's the portion I was focused on. was not focused on this questioning about, you know, oh, for example, oh, Mylan's valsartan API contained NDMA, is that right, and then your Jerusalem facility closed. None of that

is in this or in the ensuing designations.

Because what Your Honor will see is this document and another will be used to establish the foundation for the witness's 30(b)(1) and 30(b)(6) knowledge about the topics he was designated on, which include the evaluation and knowledge of risks about the creation of nitrosamines. And I'm going to use that document to establish that and walk through it.

So, again, if there's something specific that they think is going too far into the Mylan's "story," I'm happy to address it. But I don't think this designation does that. And just because the document elsewhere might say "Mylan NDEA," that's not what this designation is about.

THE COURT: All right. Victoria.

MS. LOCKARD: So, first of all, this is — they are trying to get in information about the root cause of the formation of the nitrosamines, and there's going to be a hundred other documents that establish this. Presumably, by the time Tony Binsol testifies, all of that will have been well presented.

So I don't think that -- I think it's going to be cumulative, and it's not relevant to this witness when it's coming in through the Mylan and Jerusalem story. And so in the way that it's presented here with reference to this document and setting it up through the Jerusalem facility, I do feel like this is more prejudicial than relevant. It opens up this

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     whole issue about Mylan and Jerusalem unnecessarily, and it
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     adds confusion to the jury.
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               I mean, I'm looking, I'm hearing what counsel is
     saying, and if there is a way to --
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               MR. STANOCH: And --
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               MS. LOCKARD: I mean --
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               MR. STANOCH: I'm sorry. Go ahead, Ms. Lockard.
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     sorry.
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               MS. LOCKARD: There is a reference to bullets. But I
     don't have necessarily a problem with talking about the
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     potential formation, you know. But the issue here, this
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     document with Mylan it's talking about, it goes beyond just
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     what happened in the ZHP root cause. It's saying, well, here
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     are some other ways that nitrosamines can form, some of which
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     don't even apply to the ZHP case.
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               So I really think this is prejudicial, not relevant,
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     it's confusing. I don't want to -- I don't think they need
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     this.
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               THE COURT: Well, why don't you talk about "need,"
     David, in terms of using this document to present this kind of
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     information to the jury.
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               MR. STANOCH: Yes, sir.
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               This was the document we used because it was a more
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yes, it was talking about Mylan NDEA in part, because

recent and more robust document, a Teva business record, that,

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temporally the issues came up in June with ZHP and then a few months later with Mylan, right? So this document is inclusive of all of that information before that.

And, again, four years ago we had no idea that two and a half weeks before a subclass trial, right now, that maybe, oh, we might have severed or bifurcated or informally cut out the "Mylan story" because that did not happen until much, much, much more recently. And it would be unduly prejudicial to plaintiffs to undermine the foundation and testimony, and you'll see this is testimony about NDMA formation generally.

And, again, I'm fine cutting out -- if you want to cut out part of this designation, Ms. Lockard, that says "this is a report at the Jerusalem facility, " I'm fine. But then it goes on and says there's a discussion about "the formation of nitrosamines during the tetrazole ring step, " right. talks about the conditions of which nitrosamines can form during the valsartan API manufacturing process, yes.

These are all generic things, right, about the knowledge and feasibility of NDMA formation, which this witness testified on. And it would be unfair to plaintiffs to say, oh, well, four years later you should have known that any document that also mentions somewhere else "Mylan" should have been out and then these general questions and answers, which were just used with the document to move the things along with the

witness who was testifying -- who should have been able to testify about these anyway from heart, but of course I wouldn't make him say, "give me all of the reasons for formation of nitrosamines." We use a business record to prompt that questioning, of course. That's how you do it. And that's what we did.

It would be unfair to us to say, well, sorry, you used a document that says "Mylan" on the first page. You know, you should have used one for ZHP because you should have anticipated the first trial is going to be about ZHP. You lose all of the foundational testimony about nitrosamine formation.

I think we can address this by either not showing the document during the clip or -- and taking out part of the designations that say anything -- and I thought we did -- that says anything about "Jerusalem" or "NDEA" or "Mylan," I'm perfectly happy to do that.

MS. LOCKARD: I think --

MR. STANOCH: But otherwise the entire testimony we're going to have here from Mr. Binsol, it's all going to fall apart because we were using this to show his knowledge, his and Teva's knowledge about the formation and creation of nitrosamines, generally.

THE COURT: All right. Victoria.

MS. LOCKARD: Right. So but this -- but you're not using it to show their knowledge prior to the issue, because

this is a document that came out later.

And so, you know, part of the confusion is, you know, when you take the document away, I mean, it makes it seem like you're just asking this witness about his general knowledge of how nitrosamines were formed.

I'm willing to negotiate. Maybe what -- maybe what we should do is try to offline talk about this one, because some of the information, I believe, is probably okay. But the reference to the document is problematic. The reference to things that didn't relate to ZHP, like the cross-contamination from the water supply, you know, that is not relevant to ZHP. And it's a five -- it covers five pages of testimony, so I do think it could be cut down significantly.

THE COURT: All right. Here's what I'm going to suggest: That you and David, you, Victoria, and David confer on the designations from page 43 to 48 with a view towards reducing, to the extent you can, those designations that still enables David to get the information before the jury that he'd like to present, all right, and report back to me by Thursday.

MS. LOCKARD: Okay. I'm happy to do that.

MR. STANOCH: Yes, sir.

MS. LOCKARD: I think this probably applies to the next row as well.

MR. STANOCH: I agree.

THE COURT: Let me get to the next row.

1 So this would be row 6? MR. STANOCH: Yes, sir. 2 3 THE COURT: All right. So I'll ask you to confer on 4 rows 5 and 6 and report by Thursday. 5 MR. STANOCH: Yes, sir. 6 THE COURT: So does that take us now to row 7? 7 I believe it does, Judge. MR. STANOCH: 8 THE COURT: And that would be at page 56 of 9 Mr. Binsol's transcript. 10 MS. LOCKARD: Right. 11 So, we made a number of objections to this particular 12 designation. And just to set this up, I mean, it appears 13 they've jumped now -- the testimony has jumped from talking 14 about the Teva Jerusalem investigation report of the Mylan 15 issue, which we just talked about, to now a Mylan document 16 that's providing responses to questions from Teva. 17 So, what has happened essentially in this period of 18 time is the ZHP issue has come to light. Teva is now 19 questioning other suppliers, such as Mylan, about their 20 process, do they have a similar process, do they have similar 21 nitrosamine issues, and Mylan is sending responses back. 22 So our objection in part is hearsay because there's 23 no Mylan witness in this trial. And the responses from Mylan,

there's no one here to, you know, testify to explain the

responses from Mylan. So we do think even though they're

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contained within a business document at Teva, I don't think that gets all the way through -- through the hearsay within the hearsay problem.

There's also foundation, relevance and prejudice argument for the same reasons that we're now jumping into discussions about, you know, Mylan's responses. Again, it's misleading, confusing.

So I'll just stop there.

THE COURT: Thank you. All right. David.

MR. STANOCH: Your Honor, I think it's a similar issue. Unfortunately, again, this document was being used three, four years ago, right, to establish — and this is, you know, it's a document, it's a Teva document in Teva's records, right? And these are responses to Teva's questions. So it certainly goes to Teva's knowledge of the formation of NDMA and the feasibility of being able to know about the potential formation of NDMA and to be able to characterize or identify NDMA, right, which, again, are part of the topics that were noticed per agreement with this witness.

I don't want to punt everything --

THE COURT: Sure.

MR. STANOCH: -- and come back to Your Honor in a day or two. But I don't think it would be appropriate to keep all of this out simply because we're looking now at a document responding to Teva's questions and the witness is saying yes,

that's right, that's right, in terms of formation and feasibility of NDMA because that's going to form the basis of ensuing questions in his testimony. Again, if there's some overconcern about something in particular, do we black it out, do we redact it, do we mute it out when they say it potentially?

I also don't think -- I would suggest that Judge
Bumb, you know, didn't say the word "Mylan" could not be said
here, right? We're not trying to prove anything about the
Mylan API, of course.

But, you know, they're a party opponent obviously in the case, and regardless of what -- you know, for a number of nonhearsay purposes, even if you put that aside, for the knowledge and notice of Teva about the potential feasibility and formation of NDMA, that's still germane to the noticed topics, regardless of -- you know, we're not trying to prove anything per se through this. This is establishing the witness's foundation about NDMA formation, right, which he embraces in this document that were in Teva records, and then it's used in subsequent questions.

So I'm not sure if I have a good answer for Your Honor, or if we should try to talk about it, Ms. Lockard and I, or if there's something you think more specific maybe we should focus in on here.

MS. LOCKARD: Well, on this particular -- let's just

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take this one designation at a time. So this particular designation, all it says is, you know, here's a discussion about the conditions that lead to the formation of NDMA, and that includes presence of a solvent called dimethylformamide, DMF, and the presence of sodium nitrite under acidic conditions. And so that by the time Tony Binsol gets up, like that will have been well established. So I don't know why we need to use a hearsay document to get into that with him.

I mean, I understand it's difficult. That's part of the problem of piecing these together from a video deposition, but it doesn't mean that we don't follow the evidentiary rules.

So I just don't think this is needed. And I don't want to introduce this document which was the solution or the resolution proposed by counsel in the spreadsheet because I think that takes it even farther into hearsay. I don't want to introduce this document.

And so it's unfortunate that the questioning, you know, plaintiffs' questions didn't just ask these questions instead of relying on the Mylan documents, but that's where we are. That's the testimony we have.

So I think this is going to be in already. I don't think you need to get into this with this witness through a Mylan document.

MR. STANOCH: Real quick, Your Honor.

THE COURT: That's the concern I have. Yes, go

ahead, David.

MR. STANOCH: Thank you.

This is the witness we'd get it in, Your Honor.

We've heard before, you know, and I don't mean this in any pejorative sense, we've heard for weeks now about you'll have another Teva quality person to talk about something. This is the Teva quality person. He was noticed on two different pages of topics about test results and testing and such, and more topics below about the extent of nitrosamine contamination, the use of solvents, the tetrazole ring, Teva's evaluation and knowledge of the risk of the creation of nitrosamines. So as to Teva, this is the witness we are getting it in.

And, Your Honor, if you look through this transcript, you'll see, this is part of the setup, right, that Mr. Binsol is agreeing that the steps identified here in terms of the sodium nitrite exposes — the hydrochloric acid can form nitric acid, et cetera. He confirms all of those chemistry testing, risk formation, and evaluation and knowledge issues, and then I used that in the ensuing question about it.

So, again, I think the questioning in general is appropriate. And if Ms. Lockard is saying the introduction of the document was the issue, I thought the issue was it wasn't being introduced because she wanted it to be said what it is. That's fine. I thought she wanted to make clear that it's a different document than the one prior.

But if this is -- if this Teva witness is not the one, the one who's the 30(b)(6), the quality person to talk about this, we don't have any -- we don't have any Teva person. And I don't think that's an appropriate basis to keep out this testimony.

THE COURT: All right.

MS. LOCKARD: I've never said he's not the right witness to talk about quality issues. He is. But the questioning, you're asking this witness a question about the Mylan Q & A, not about the ZHP issue.

And what I'm hearing now, I've heard you say "notice," it shows notice a couple of times. And that really gives me pause with respect to the prejudice and 403 and misleading objections. Because if you're trying to use this to suggest that Mr. Binsol had notice of these issues before the ZHP issue, that's a misuse of this document. Because the document you're questioning about, you're saying here's what it says, and he says yes. I mean, you're basically going through the document and he's saying yes, that's what it says, that's what the discussion with Mylan was. That's what it says.

But there's no acknowledgment or concession that he knew or that Teva knew all of these things before the ZHP issue came to light.

So for notice, it has no relevance. It doesn't show notice. All it shows is that they knew that this was the root

cause because ZHP told them that was the root cause, and FDA confirmed it all after the fact.

MR. STANOCH: If I misspoke, that was not my intention.

THE COURT: Go ahead, David, quickly.

MR. STANOCH: I'm sorry. Thank you, Judge.

If I misspoke, that wasn't my intention. The point is that Teva is going to agree that even after the fact quote-unquote that this is how nitrosamine formed, then we're going to show with other information that there was other information. So that's knowledge of how it can form. That's not — I'm not saying notice, this tipped you off in 2011 or something before the recalls. I'm saying you're agreeing with this knowledge as a fact that this is how nitrosamine can form, right, as a general matter, right?

And then later in the deposition I juxtapose that against earlier-in-time documents, including those in Teva's own records, right, which talk about the same thing about nitrosamine formation, right? And I think we're allowed to say Teva acknowledges NDMA can form in manner A, and then compare that to other documents prior in time saying isn't this document in Teva's possession, saying the same thing about how NDMA can form in the manner A, right? And I can put those two things together.

I'm not trying to say this tipped off Teva about the

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potential in the past. This particular document is saying we're establishing the baseline, we're on the same page. NDMA can form under these conditions. Yes. And then use that later to say these documents you had from the past, right, talk about those same conditions. Those are two different things. This is part one of the equation.
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THE COURT: Well, I'm not sure what the equation is, but I will overrule the objection. I think this is relevant, probative evidence. I know there are hearsay objections, but I can't tell from the exchanges that are at issue on these pages of the transcript that there is a hearsay problem, and we'll allow it.

MS. LOCKARD: Understood, Judge.

MR. STANOCH: And I think, Judge --

THE COURT: I think we're to row -- go ahead. I'm sorry.

MR. STANOCH: Oh, I was just going to say I think that would get us -- because this line of questioning goes through from row 11, and the next sort of area of questioning would be row 12, beginning at page 66.

MS. LOCKARD: So --

THE COURT: So you're saying this gets us through rows 7 through 11?

MR. STANOCH: Yes, I think that's right. And, again,
I am happy when we -- if I'm wrong, Ms. Lockard can correct me.

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and no question.

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And in our going through meet-and-confer, I'm certainly happy
if there's particular things that we can address and excise
from what you just allowed, I'm happy to do that.

THE COURT: Go ahead, Victoria.

MS. LOCKARD: So I don't necessarily agree with that.

I mean, if we just take exhibit -- or take row 8, for example,
one of our issues is that this just starts up with the answer
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MR. STANOCH: I -- if that was -- I will -- there's no counterdesignation there from Ms. Lockard. I'm happy to add the question back in on page 57, if it was cut out.

MS. LOCKARD: Well, yeah. We did have a counter, 57:11 to 57:14, if it's brought in.

MR. STANOCH: I will agree.

THE COURT: All right. So that's in.

Anything else, Victoria?

MS. LOCKARD: Yeah. I mean, this is -- I guess if we're not dealing with the -- we're going to make -- we are going to make an objection to this document, and there is some uncertainty about how we're going to handle this, because in this particular designation, he's talking -- he's pointing out a specific diagram on the document. And so, you know, we don't believe this document -- this exchange between Mylan and Teva should come in. We do think it's a hearsay document. Mylan is not a party opponent in this trial.

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And so I think -- I mean, I understand this goes part and parcel with the Mylan discussion, but we're going to have to -- if the document's out, this testimony can't come in, because he's looking -- talking about a diagram that's on the document that won't make any sense to the jury if the document is not in. That's not background information about how this forms.
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MR. STANOCH: Pending an outcome of objections to exhibits, we may have to revisit certain of these designations.

THE COURT: Well, when are those objections to exhibits going to be presented?

MS. LOCKARD: I --

MR. STANOCH: Frankly --

MS. LOCKARD: I emailed Mr. Stanoch over the weekend when I sent Mr. Nudelman's -- or not over the weekend, but when I sent Mr. -- Dr. Nudelman's and I said you need to let me know which exhibits you plan to introduce with these witnesses so that we can hash out any objections we have to them and get them heard by the Court.

So we don't have a -- we don't have an exact timeline for that with the Court yet.

THE COURT: All right. So -- go ahead, David.

MR. STANOCH: I was just going to say, I can't speak for my entire side, Your Honor. There's a lot of moving targets in terms of the PTO. As Your Honor knows, you'll be

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     having a hearing at the end of the week on that, and I know the
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     parties, I assume, would have exhibit lists, but I would agree
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     that I'm not -- I'm personally not sure what the exact timing
     would be.
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               THE COURT: All right. So my ruling is that this
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     testimony that is covered by row 8 of the spreadsheet, that
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     testimony is subject to an examination...
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               The exhibit used in that examination cannot be used.
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     And if that's the corresponding testimony...
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               THE COURT REPORTER: I'm sorry, Your Honor.
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               (No audio.)
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               (Court reporter interruption.)
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               THE COURT: Row 8 of the spreadsheet... testimony is
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     subject to...
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               (Audio indiscernible.)
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               THE COURT: Yes. The examination that is covered by
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     Teva in row 8 of the spreadsheet, if... then the testimony will
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     not come in.
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               (Court reporter interruption.)
               THE COURT: Counsel, are you able to hear everything?
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               MR. STANOCH: I could not. I'm having trouble
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     hearing Your Honor.
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               THE COURT: All right. I don't know why that's the
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     case.
               (Discussion was held off the record.)
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               THE COURT: Let's try one more time. All right.
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               And my ruling is that if the exhibit that is the
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     subject of the testimony that's covered by row 8 of the
     spreadsheet is excluded, then the corresponding testimony will
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 5
     be excluded.
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               Were you able to hear that?
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               THE COURT REPORTER: Yes, Your Honor.
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               MR. STANOCH: Yes, Your Honor.
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               THE COURT: All right. Victoria?
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               MS. LOCKARD: I could hear. Thank you.
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               THE COURT: All right. Okay.
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               MS. LOCKARD: So I think there was also just, Dave,
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     Mr. Stanoch, I don't think you included the answer at the end
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     of that designation on line 8. So I assume you agree to
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     include that as well. I don't think we countered that because
     I didn't notice that was cut off.
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               MR. STANOCH: Agreed. Will be added. If it was cut
18
     off, it was an accident.
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               THE COURT: All right.
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               MS. LOCKARD: Okay. So that takes us to row 63. And
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     we did have some counters that we designated for this.
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               THE COURT: Yeah. That takes us to row 9.
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               MS. LOCKARD: Excuse me. Row 9, yes.
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               THE COURT: Yeah. Page 63 of the deposition.
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               And you had counters that start at page 61 of the
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     deposition, correct?
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               MS. LOCKARD: Correct. Yes.
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               MR. STANOCH: I'll agree to them.
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               THE COURT: All right. So the counters are agreed
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     to.
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               Does that resolve your objection?
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               MS. LOCKARD: It does. I don't -- I did not have any
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     objections, just the counter. So I think that resolves row 9.
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               THE COURT: Okay. So row 9 is resolved.
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               Let's go to row 10. And this concerns the testimony
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     at page 64, lines 5 to 9. The objection is Rule 403.
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               MS. LOCKARD: Right. This is -- to me, we objected,
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     403. I mean, it is vague, confusing and misleading.
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               I don't know what's meant by available literature.
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     If he's talking about -- I mean this witness was designated on
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     testing and levels. So is he talking about that available
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     literature? If he's talking about other available literature,
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     then I quess it would be personal knowledge and outside the
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     scope.
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               But I think this question is just vague and
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     confusing. And it doesn't provide anything relevant to the
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     process because he says he's not aware.
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               THE COURT: Yeah. David.
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               MR. STANOCH: Your Honor, I think the question is
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     relevant, and, in fact, I just agreed to the counters of the
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questions and answers both immediately before and immediately after this. The witness was designated on more than just testing. He was also designated on knowledge of the risks of creation of nitrosamines, the risks and knowledge and evaluation of the health risks of nitrosamines and other such topics. He answered the question. He's clearly saying that he's not aware of this particular process, and then I follow-up about patent information, and he has no problem answering that information, all in questions that counsel for the defense have just counterdesignated above in row 9 which we agreed to let in.

So I don't think there is anything that falls within Rule 403, and certainly nothing under vagueness or form given that the witness was able to answer it. And in the ensuing questions and answers that have been counterdesignated, he's clarifying information to the best of his knowledge.

THE COURT: Yeah. Given the fact that the testimony covered by row 9 of the spreadsheet is coming in, I think that clarifies and makes understandable the question that appears at line 5 of page 64 going through line 19 on page 64. So this covers, in my mind, rows 10 and 11 of the spreadsheet.

MR. STANOCH: Understood, Judge.

THE COURT: All right. So they'll come in. Objections are overruled.

MS. LOCKARD: Okay. And let me just make a

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clarification point on the record.
                                   I think counsel has
overstated the topics that this witness was designated on.
wasn't designated on the risk -- the knowledge of the health
and safety risks. That was Dr. Nudelman.
          THE COURT: Okay.
         MS. LOCKARD: So I don't know that --
         MR. STANOCH: I don't want to belabor --
         THE COURT: It doesn't affect my ruling, though.
         MR. STANOCH: Okay. Yeah. I'll stop.
         MS. LOCKARD:
                      Okay. So that takes us to row 11.
          THE COURT: Okay.
         MR. STANOCH:
                       That was just the answer to the one
above it, Ms. Lockard.
         THE COURT: I think it takes us to row 12.
         MS. LOCKARD: Yes. Okay. Just making my note here.
         MR. STANOCH: Thank you.
         MS. LOCKARD: All right.
                                   That takes us to row 12.
         MR. STANOCH: Agreed.
         MS. LOCKARD: We had an objection as to the
foundation, relevance, and hearsay. This is a discussion --
plaintiffs are asking about this patent. It's actually a
Chinese patent application.
          So I know that this was discussed with the ZHP
witnesses, and that's a little bit different because it was a
document that was within the ZHP witnesses' document production
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and in their business records. And I understand the line of questioning and the Court's rulings on that there.

Here, it's a little bit different. This is a Chinese patent application that counsel has pulled out and is asking Mr. Binsol about this, and we do have objections to this, a number of objections to this. This is not something that is shown that was ever produced by Teva or that was ever seen by Teva or that this witness is aware of. This witness was certainly not identified on issues related to patents. You know, I don't think this document has been authenticated. It is a Chinese patent application that appears to be pulled off of a Google website.

And so although to ask ZHP about it, it was in their production, that's one thing. To ask Mr. Binsol about it we think is lacking in relevance, it's prejudicial, and it's hearsay.

THE COURT: All right. David.

MR. STANOCH: Thank you, Your Honor.

First, Ms. Lockard's correct that this is a publicly available version of the same patent which was attached to the ZHP email which Your Honor has heard so much about. And on one level the document fairly goes to the knowledge of N-nitrosamine formation, which is clearly within the topics on which he was noticed.

I'm not saying notice at this yet. I'm saying the

witness agrees that this document does reflect his and Teva's understanding about the creation of nitrosamines in terms of how it -- what it lays out in terms of valsartan API. That's number one.

Number two, Your Honor, the document has a number then of nonhearsay purposes which flow through that.

Number one is that it's establishing that there was a notice of a danger. That's not hearsay; that this document was publicly available years prior, years prior to the recalls, and that Teva is acknowledging that what it says is correct in terms of NDMA formation and how — and the feasibility, by the way, of if you remove the sodium azide, you're not going to get the NDMA, how it's feasible to have valsartan without NDMA formation. They're acknowledging that's correct and that it existed years prior. And then further, the witness acknowledges I wasn't aware of that and Teva wasn't aware of that, because he was the designee on Teva's evaluation and knowledge of the risk of the creation of nitrosamines, including NDMA.

So in addition to that, Your Honor, it's also not hearsay because we're not trying -- it's a public record, I might add. And courts often take even judicial notice of patents, patent applications, and prosecution history. But the fact that there's published scientific literature and publicly available information is highly relevant to the defendants'

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knowledge or the ability and feasibility of understanding a potential defect or a danger in a product. And that's the classic nonhearsay purpose which is allowed.

And, again, this witness was designated on these topics, agrees with the NDMA formation discussions, and that this information is the same information, in fact, of what we were talking about a few rows earlier, right, when we were looking at that Q & A and other documents, right, where I asked him, you agree NDMA can form under these conditions? Yes? He says, "Yes." That was sort of knowledge writ large.

Now we've linked that up and said, well, here's that same knowledge which you agree shows you how NDMA forms. Here it is in the public sphere years ago, right, and you agree it's the same and you say we didn't know about it. I think that's relevant and probative.

MS. LOCKARD: So, first of all, that's a mischaracterization of this document. This witness says that he's responding to the references to the generation of Impurity K. And plaintiffs can argue that, you know, their interpretation of this is that it establishes the presence of NDMA. That's their argument. But this document and this witness talks about the generation of Impurity K in this document. So it does not go to show notice of formation of NDMA.

Secondly, it doesn't go to show notice by Teva of

anything, because Teva didn't have this document in their materials, unlike ZHP. ZHP had it in their files; Teva didn't. This has never been established with this witness to be a publicly available document. It was a Chinese patent application. And U.S. courts, courts will allow U.S. patents to be presented typically either if they are properly authenticated or if there's a certified version from the patent court or on occasion they will take public notice. But I have not been able to find any evidence of a court in the United States, and we've looked, taking judicial notice of a Chinese patent application off of Google. And even the patent courts in the U.S. don't allow evidence of patents via Google patent. It has to be an official document.

So we don't think that -- the fact that this was pulled off of Google and put into ZHP's file without proper authentication, without establishing through this witness that this witness or Teva would have had public access to it is inappropriate.

I mean, the bottom line is it's just not relevant to this witness and to Teva. Teva didn't have it. They didn't see it. It doesn't show notice.

Plaintiffs like this document, and they're going to have plenty of time to talk about it with ZHP, but it shouldn't come in through Tony Binsol.

THE COURT: All right. David, final word on this.

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               MR. STANOCH: Thank you, Your Honor. I'll be very
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     brief.
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               THE COURT: All right.
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               MR. STANOCH: We asked this witness, who again is
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     known -- is the 30(b)(6) on evaluation -- on formations and
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     knowledge -- formation of nitrosamine and knowledge of how
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     nitrosamines can form. And I say: "This patent is saying if
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     you don't use sodium nitrite in the manufacture of the
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     valsartan API, you're not going to get the nitrous acid.
                                                                And
     that was one of the components that we agreed could
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     theoretically lead to the formation of NDMA, right?
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               "Answer: Right."
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               And then he goes on, and we go back and forth some
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            And then I say, well, did Teva ever search for this
     document, this publicly available information before?
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               And he says, well, I don't think so.
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               And you'll recall, Your Honor, testimony earlier
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     about does the quality department or anyone at Teva actually do
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     a public search for public information which merely puts folks
     on notice, a nonhearsay purpose, about the potential danger or
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     the feasibility of a product characteristic and what its
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     effects might be for the formation of NDMA.
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               And I think it's highly relevant and certainly
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     probative, and a jury can infer that there is publicly
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available information, whether or not -- we're not trying to

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prove NDMA forms based on this patent alone, right? But the fact that there was out there in the prior art a publicly available document that you could get on the Internet years earlier and Teva never got it, that that certainly goes to the quality and the appropriateness of its quality oversight of ZHP, that it would never even have bothered to even look for something like this, let alone what it says or not; that they never even thought to look for it years ago when it was sitting out there in the ether, which we can argue about what the patent does or does not say about Impurity K or nitroso compounds, but that's a different issue.

And this goes to what Teva did or did not do years prior with the information in the public sphere that was available to put them on notice and to warn the public in general about knowledges in the prior art of design defects or potential unreasonable dangers of the product.

MS. LOCKARD: See, this is why I objected to the question about available literature, because now they want to shoehorn that response into suggesting that, oh, that Teva has some obligation to look through all the available literature, which means Chinese patent applications, and it's so tenuous and prejudicial at this point that I'm smiling because I can't believe that this is — that this is the core evidence that they want to rely on.

But it's not even a patent, Your Honor. I mean, it's

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an application in China. It's going to come in through ZHP. I mean, there's -- there's no -- there's no testimony. didn't set this up with this witness. He didn't set it up with this witness to show that it was publicly available in the appropriate way to authenticate it, to ask this witness, does anybody at Teva do patent searches? Does anybody look at the Chinese patent applications? They didn't set it up in that way and it's therefore not admissible and it's prejudicial.

MR. STANOCH: Ten seconds, Your Honor.

THE COURT: Ten seconds.

MR. STANOCH: I specifically asked the witness, right, who, again, is the corporate witness on Teva's knowledge about the formation of NDMA, I asked him if he's aware of it, if anyone at Teva became aware of this patent and its examination of the nitrosamines. He says I can't -- he says I'm not aware of it. I said, are you aware of anyone else discovering this patent at Teva? So I did ask him about what, if anything, Teva did at the time.

Leave it at that.

MS. LOCKARD: But under 611(a), it's not even accurate. It's not even a patent. I mean --

MR. STANOCH: The witness -- I'm not going -- I'm sorry. I don't want to dicker, Your Honor.

THE COURT: Yeah. My initial inclination was to sustain the objection to this line of testimony, which is

covered by, correct me if I'm wrong on this, rows 12, 13, and 14 of the spreadsheet.

MS. LOCKARD: I mean, I guess if he wanted to simply ask, you know, was Teva -- was anybody at Teva aware of the patent and there was a question do you know if ZHP ever disclosed the existence of the patent, and he says I'm not aware, I guess with those -- you know, maybe there could be a compromise with those two questions. But I think that's as far as it should go under these evidentiary rules.

THE COURT: See, what I had a problem with, David, is the question at line 18 of page 74 of the transcript where you ask: "Can you think of any reason why Mylan or ZHP would not be able to find this publicly available patent concerning the preparation of valsartan API?"

And first I think the question is misleading in terms of you're talking about this patent when we're talking about a patent application. "And can you think of any reason," I just don't think that's a proper question.

And it sort of -- that tied up the whole line of inquiry. And so I'm going to sustain the objections that are covered by rows 12 --

MR. STANOCH: I would agree to the question and answer you highlighted, Your Honor, to withdraw that.

And I'd also, just to correct the record, the document itself, the patent application was granted and

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     published. That's what it says. It's not just a patent,
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     quote, patent application --
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               THE COURT: Okay.
               MR. STANOCH: -- in Chinese.
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               First of all, it's all in English, all translated,
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     and it was granted and published. So I'm just stating that for
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     the record, Judge.
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               THE COURT: All right.
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               MR. STANOCH: So it's a patent. It's not a patent
10
     application.
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               MS. LOCKARD: It's not a patent. I will get a
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     certificate, a declaration from my patent colleague who looked
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     at this.
               It is not a patent.
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               MR. STANOCH: Well --
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               MS. LOCKARD: So it's misleading, and it's
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     misrepresenting what this is. And that's the underlying
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     problem with it.
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               MR. STANOCH: I think we're getting far afield --
               THE COURT: Well, I'm going to sustain the objections
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     for the testimony covered by rows 12 and 13 and 14 of the
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     spreadsheet.
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               And I think that takes us to row 15.
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               MS. LOCKARD: Right. And, Your Honor, I think just
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     the first -- that row 15 also deals with the patent. The first
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     part is the answer to the question that you sustained the
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     objection on, and then there's a new question.
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               THE COURT: What line are we on, Victoria?
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               MS. LOCKARD: That would be -- it's page 75, line 1
     to 11.
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               THE COURT: Okay.
 6
               Yeah.
                      That should be out.
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               MS. LOCKARD: Then that takes us to 16, row 16.
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               MR. STANOCH: I'm sorry. I didn't understand the
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     answer to the prior one. 75:6 to 76:11, right, that's
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     different, that's asking a different question.
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               It was -- in fact, it was your contingent counter.
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                            Right. Only if it came in. But --
               MS. LOCKARD:
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               MR. STANOCH: Given this, I'll say that I'd ask for
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     it to come in then.
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               MS. LOCKARD: I will agree to this line 6 to 11.
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               THE COURT: On page 75?
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               MS. LOCKARD: Correct.
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               MR. STANOCH: Thank you.
               THE COURT: All right. That's it.
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               MS. LOCKARD: Okay. Can you -- can you edit out the
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     word "Mylan"? Is that -- are we going to fight about that?
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               MR. STANOCH: Well, we'll -- we'll deal with it.
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               MS. LOCKARD:
                             Okay.
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               Okay. So row 16, page 79.
               THE COURT: That's what I have.
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MS. LOCKARD: Yeah. So this is questioning about the EPA technical fact sheet, and I do -- you know, I do have a relevance and a prejudice objection here. This is an Environmental Protection Agency document. It really -- the reason they're bringing it in relates to some of the carcinogenicity issues. So I had made a note, "this is subject to the GC ruling, "because they're bringing this out to say that EPA calls it a potent carcinogen. So we really object to that entire question and answer. THE COURT: So this covers the testimony from page 79, line 24 through page 85, line 7. MS. LOCKARD: It's such a long designation. why I'm pausing because there's a lot of information in here that I think is subject to the GC ruling. With that aside, there is a lot of irrelevant testimony that is in this designation that derives from this EPA technical fact sheet. So I just don't think that, aside from -- if general causation is out, as plaintiffs say, then I just don't think there's any relevance left to this document whatsoever. And that's why we objected to the entire designation. THE COURT: David. MS. LOCKARD: Plaintiff --MR. STANOCH: In terms of quote-unquote general

I mean, literally defining what NDMA is, as a semi-volatile

causation, yes, I mean, part of this, you know, may talk about,

compound with carcinogenic potential. Sure, you know, we'll see what Judge Bumb says on Thursday about that. But as to the rest of it, I think it's certainly relative -- relevant, Your Honor, right, that it's a document predating all the recalls, talking about the nature of NDMA.

And I think it's important to note, too, that the EPA is talking about nitrosamines in water, and that's important because ZHP in 2017 stumbled upon NDMA in connection with testing its wastewater in the manufacture of valsartan, right? So I think the discussion about how NDMA in water and wastewater and things of that nature is all part and parcel of the overall story. And this is showing, you know, Teva's notice and knowledge of at least part of those facts which are one of the reasons that were identified ultimately as being an issue giving rise to the NDMA formation of the valsartan API manufactured by ZHP.

THE COURT: I guess the concern I have here, and maybe you can help me with it, David, is there was no mention of pharmaceuticals in this article that you're using for the examination of this witness.

MR. STANOCH: I don't -- I don't think, Your Honor, that a document has to say specifically that NDMA can form in the manufacture of a pharmaceutical drug to be relevant. It can say that in manufacturing, industrial and other processes, right, the chemistry, the underlying chemistry formation,

chemical formation of NDMA could arise when you're processing things using aqueous solutions, i.e., water, which in the NDMA, one of the root causes identified and what actually happened was that there was ZHP testing its valsartan manufacturing process wastewater and found NDMA.

And I think that the fact that all — that the EPA is acknowledging a variety of processes, right, industrial uses and processing facilities, right, that the chemical reactions happening there could result in NDMA forming, I think that's probative of whether it could form in this manufacturing process even if the word "pharmaceutical drug" does not appear in the article.

THE COURT: All right.

MS. LOCKARD: Well, we obviously don't think it's relevant for that reason. You know, no one disputes that NDMA was a compound that existed prior to it being discovered. I don't think that's at issue. The issue in the case is whether or not the manufacturers knew or the industry knew that it could form in pharmaceuticals. And this doesn't say that. And so I think it's misleading to the jury to suggest that this presents notice of something that it doesn't give notice of.

MR. STANOCH: Well, ten seconds, Your Honor.

THE COURT: Yes.

MR. STANOCH: This document predating the recalls talks about in a variety of processes that chemical reactions

can occur to lead to the formation of NDMA, specifically in byproduct wastewater. And then these questions culminate in then, hey, did Teva ever ask ZHP whether ZHP considered the use of nitrous acid in the manufacture of valsartan that could lead to the creation of NDMA, just like this EPA article is talking about, and he says I'm not aware of it.

MS. LOCKARD: But the article is talking about pesticide manufacturing plants, you know, rubber tire makers and, you know, fish processing. So --

MR. STANOCH: Right. If it can happen in these dozen other things, I can argue to the jury, Judge, I submit, that it's reasonable for a sophisticated global pharmaceutical manufacturer to exercise its quality cGMP oversight of its supplier and say, hey, in your manufacturing processes, just like it can happen in all these other 15 different things, are you keeping tabs of this. And they never even asked the question. And then that ended up being one of the identified root causes for the contamination of NDMA of valsartan made by ZHP. And Teva never even asked the question.

THE COURT: Right. Yeah. I'm persuaded that this line of inquiry is appropriate and the objection is overruled.

MS. LOCKARD: Okay.

THE COURT: And that should take us through row 17 and now take us to row 18.

MR. STANOCH: I think so.

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1
               THE COURT: And that's the testimony that starts on
 2
     line 5 of page 91.
 3
               MS. LOCKARD: Okay. I'm getting there.
 4
               MR. STANOCH: Yes, Your Honor. I think this line of
 5
     questioning -- I mean, we can see it. I think this line of
 6
     questioning on this document will go through line 22, 96:4.
 7
     I'm not trying to preempt Ms. Lockard's objections.
 8
               THE COURT: No, no.
 9
               MR. STANOCH: I'm just trying to say the next five or
10
     six I think are very related.
11
               THE COURT: Yeah.
12
               MS. LOCKARD: Yeah. That's what I was looking at to
13
     see.
14
               So --
15
               THE COURT: So this would take us -- I'm sorry to
16
     interrupt, Victoria -- take us from row 18 through row 22.
17
               MS. LOCKARD: I think that's right, at least.
18
               THE COURT: Okay. At least. So let's cover that.
               MS. LOCKARD: Okay. Right. So I think this is --
19
     we've made objections to these articles similarly as we have
20
21
     before to the scientific literature that plaintiffs have used
22
     to question our fact witnesses. We do believe there is a
23
     hearsay objection there; that it doesn't fall within the
24
     learned treatise exception because it hasn't been established
25
     as being reliable through an expert, and it's not being used
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with an expert. So we think that this is an inappropriate use of the literature.

We also have made the objection based on relevance and prejudice, but importantly, this 602, lack-of-personal-knowledge and outside-the-scope objection is important because this witness obviously was not here or identified to talk about the state of the scientific literature and whether NDMA had been noted in the literature prior to the discovery.

He was identified to come in and speak about the actual testing results that Teva undertook and what was going on with their testing program and how they, you know, were testing for impurities. It wasn't a witness who was identified to come in and talk about, you know, all of the literature in the public referencing NDMAs.

So that is the gist of our objection on this section and these multiple articles.

THE COURT: All right. David.

MR. STANOCH: Thank you, Judge.

The questioning is about an article from 2012 produced from Teva's files with a custodial date of 2011 about the overall impact of the regulatory requirements for genotoxic impurities of the drug development process. And it goes on at length to talk about the testing of pharmaceutical products for genotoxic impurities. And Mr. Binsol, aside from being

designated on topics about knowledge and evaluation of risk of the creation of nitrosamines, was designated on any number of topics regarding testing and testing used in conjunction from a quality standpoint, including testing limits used for the product. And this article specifically talks about FDA guidance on genotoxic and carcinogenic impurities and the limits or lack of limits for such impurities like nitrosamines.

And this was — this, more than some other articles that maybe we talked about earlier today or definitely versus the patent, this was in Teva's possession in 2011, right, and it was sent around by emails in 2014 within Teva about it. It certainly is probative of Teva's knowledge prior to the recalls about the impact of the regulatory requirements of testing and potential formation for genotoxic impurities during pharmaceutical drug process development.

And the witness had no issue answering the questions and went through the questions. And, Your Honor, I believe that Mr. Karlsson the other week, you did let in one article because it was, you know, it was within Teva's possession. I won't say -- you -- I won't want to argue about it, but you did let in an article. This is very similar to that article and the articles that you've let in I believe with the ZHP witnesses, right?

And this is not something like the patent which I put in front of him, which he hadn't seen, or Teva didn't Bates

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This was their records. It certainly shows the
stamp.
nonhearsay purpose that they were on notice about all of this
information about the testing of genotoxic impurities,
including nitrosamines.
          THE COURT: Yeah. I'll overrule the objection to
this line of inquiry. I think it is relevant for purposes of
showing notice and will allow it.
          And I think that takes us now to row 23.
          MR. STANOCH: I believe you're right, Your Honor.
But, again, I'm not trying to cut off Ms. Lockard, but I think
that's right.
          MS. LOCKARD: Yeah. I think that's generally right.
I think I had one more note.
          THE COURT: All right.
          MS. LOCKARD: Just let me check that and see if this
resolves it.
          Actually, I think it does. So I think you're right.
          THE COURT: And the inquiry on page 98, starting at
line 11, which is addressed in row 23 of the spreadsheet, seems
to be dealing with another article.
          MS. LOCKARD: Right. I think there were two.
just get there.
          One of the issues, aside from the article, this
designation is getting into the sourcing of API from Hetero for
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losartan. This -- I mean, if he wants to -- under your

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part of row 23.

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rationale, if he wants to ask about the article and the date of
the article and the title of the article, I think that's okay.
But then when we get to line 3 of page 99 and it's asking about
one of the authors is someone affiliated with Hetero, who is a
codefendant in valsartan and the losartan litigation, I think
this part should come out, Your Honor, based on relevance and
confusion.
          David, do you have any objection to that?
          MR. STANOCH: I'm trying to get to where you're
looking at.
          MS. LOCKARD: Sorry.
                                It would be --
          THE COURT: Page 99.
          MS. LOCKARD: -- page 99, line 3. Line 3.
          MR. STANOCH: Well, a moment, Your Honor. I just
want to get there.
          I -- I think it -- I think I'd leave in the question
about that the authors were affiliated with Hetero, and he
answers "yes." I don't see an issue with that. It sounds like
Ms. Lockard's issue is that Teva sourced some API from Hetero.
          Yeah, I'd be okay withdrawing 99:8 through 100:8,
which is I quess specific questions about Hetero losartan.
          So I would agree to withdraw the question beginning
at 99:8 through the answer of 100:8.
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MS. LOCKARD: So that would take care of row 24 and

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1
               MR. STANOCH: Uh-huh.
 2
               MS. LOCKARD: But you want to leave in the question
 3
     about "among the authors of this article is someone who is
     affiliated with Hetero Drugs." Why do we need that? That's --
 4
 5
     they haven't -- they're not going to have heard about Hetero.
 6
     That's 99:3 through 7.
 7
               MR. STANOCH: Fine.
 8
               THE COURT: All right. They're out, too.
 9
               MR. STANOCH: 99:3 through 100:8, I will withdraw,
10
     Your Honor.
11
               THE COURT: Okay.
12
               MR. STANOCH: I'm sorry we could not have done this
13
     prior to today. We're both working hard, Judge Vanaskie.
14
               THE COURT: I know you're working very hard.
15
               MR. STANOCH: I apologize we couldn't have done this,
16
     but --
17
               MS. LOCKARD: But we have resolved a lot, a lot. So,
18
     Your Honor, you should know that. We have resolved a lot of
19
     things.
20
               THE COURT: And I greatly appreciate that. Thank
21
     you.
22
               So where are we at now?
23
               MS. LOCKARD: Row -- well, row 25, page 100, line 16,
24
     and I think he's still talking about the article.
25
               MR. STANOCH: Uh-huh. Yes.
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1
               MS. LOCKARD: Let me get to the bottom.
 2
               I think under the Court's prior rationale, I think
 3
     that probably comes in. So I think that flows from the ruling
     on the articles. So we'll accept that.
 4
 5
               THE COURT: All right.
               MS. LOCKARD: And I think that would include -- with
 6
 7
     that coming in, we would agree to...
 8
               THE COURT: It seems to me --
 9
               MS. LOCKARD: Oh, I see. The answer is designated,
10
     but I don't think the answer made it on our sheet, because I
11
     didn't really have an objection to the answer.
12
               MR. STANOCH: I see. Okay.
                                            So 104:22 is a question,
13
             We're okay with the question. And, Ms. Lockard, we'll
     right.
14
     try to mute out "Mylan" or something if you're okay with that.
15
               MS. LOCKARD: Wait. No. I'm not there yet. Sorry.
16
               MR. STANOCH: Oh, I'm sorry. I thought you were
17
     there.
18
               MS. LOCKARD: Sorry, Mr. Stanoch.
19
               I was looking at -- so we had just talked about row
     25, which is 100:16 to 104:9.
20
21
               MR. STANOCH: I'm with you.
22
               MS. LOCKARD: Okay. And then the question -- that's
23
     the end of the question -- and then the answer is at 104:13 to
24
     17, and I didn't see that on the dispute chart. But I think
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I -- I just confirmed that you had actually designated that, so

25

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1
     I think that's in.
 2
               THE COURT: Okay.
 3
               MR. STANOCH: Right.
               THE COURT: Because that was not designated. That
 4
 5
     was not on the spreadsheet provided to me.
 6
               MR. STANOCH: Right.
 7
               MS. LOCKARD: Yeah. Okay. So I think we got that
 8
     resolved on our own.
 9
               THE COURT: Okay.
10
               MS. LOCKARD: So then I'm on 104:22, sorry,
11
     Mr. Stanoch, I cut you off.
12
               MR. STANOCH: No, please. I was just saying at
13
     104:22 at the end of that question we can try to mute out
14
     "Mylan." I'm fine, or "Mylan." And then I think the rest of
15
     that would come in, that ensuing question and then the next
16
     line, the answer, but take a look.
17
               THE COURT: So why not simply eliminate lines 19
18
     through 21 of page 104?
19
               MR. STANOCH: I agree.
20
               THE COURT: So that comes out. Are you with us,
21
     Victoria?
22
               MS. LOCKARD: Yes, I'm with you.
23
               THE COURT: All right.
24
               MS. LOCKARD: But then the reference to Mylan at
25
     line 24, you would need to edit out.
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1
               MR. STANOCH: Yeah. We'll just -- we'll stop at
     "assessment by ZHP." Is that acceptable?
 2
 3
               MS. LOCKARD: Yes.
 4
               THE COURT: All right.
 5
               MS. LOCKARD: I mean, we had objections here which I
 6
     don't -- which I don't -- I'm not withdrawing. But I know
 7
     where Judge Vanaskie is going on this one, so ...
 8
               THE COURT: Yeah. I mean, I would allow it as long
 9
     as you could edit out the reference to "Mylan."
10
               MS. LOCKARD: Right. So 105, so this was the answer
     at 105:13, to 105:19, so I think that goes along --
11
12
               MR. STANOCH: Yes.
13
               THE COURT: Yes, it does.
               MS. LOCKARD: -- with your ruling.
14
15
               Row 28, we jump to page 134.
16
               MR. STANOCH: I'll withdraw row 28 which begins at
17
     134:18.
18
               MS. LOCKARD: Yeah. That was the Jerusalem issue.
19
               Okay. So that's out.
20
               Right, Judge? Are you with us on that one?
21
               THE COURT: I'm with you on that. So the testimony
22
     covered by row 28 starting at page 134, line 18 through 136,
23
     line 7 is out.
               That takes us to row 29, which jumps ahead to
24
25
     page 171.
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1
               MS. LOCKARD:
                             Okay.
 2
               MR. STANOCH: And you know what, Your Honor, to help
 3
     us move along, I may even withdraw this one, too.
 4
               MS. LOCKARD: Please do, because it's totally
 5
     confusing and not relevant.
 6
               (Laughter.)
 7
               I may be hurting my case. I don't -- I mean, we're
 8
     going to have to spend time explaining it if so, and...
 9
               THE COURT: So you want to withdraw the testimony
     covered by row 29?
10
11
               MR. STANOCH:
                             Yes.
12
               THE COURT: And the counters as well?
13
               MS. LOCKARD: Yes, we will withdraw those.
               THE COURT: Okay. All right. Row 30, page 184.
14
1.5
               MS. LOCKARD: Just give me a moment, Your Honor.
16
               THE COURT: Yeah. I have to read through it myself.
17
               MS. LOCKARD: So, the issue here is that at the time
18
     of Mr. Binsol's deposition testimony, there was some
19
     uncertainty about the nature of the testing and actually what
20
     testing was done. And the documents that he was shown, he
21
     couldn't answer the question from the documents that he was
22
     shown, but the answer was in other documents. And I objected
23
     on this because I think it gets very confusing throughout this.
24
     But, you know, I think I'll withdraw the objection here because
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I think, in fairness, the witness was disclosed on testing, so

25

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1
     I think Mr. Stanoch is probably going to be allowed to ask him
 2
     this question -- these questions. So --
 3
               THE COURT: So what is covered here? Rows?
               MS. LOCKARD: So row 30, and then, yeah, it's just --
 4
 5
     that just goes to the designation at row 30.
 6
               THE COURT: Okay.
 7
               MS. LOCKARD: So we'll withdraw, so that will come
 8
     in.
 9
               THE COURT: That will come in.
               MR. STANOCH: Tell you what, Your Honor, in the
10
11
     spirit of compromise, Ms. Lockard withdrew the objection to row
12
     30, I'll withdraw the designation at row 31.
13
               (Laughter.)
14
               MS. LOCKARD: Okay.
15
               MR. STANOCH: We can split the baby ourselves,
16
     Counsel.
17
               THE COURT: Good. All right.
18
               So we're at row 32 now. Now, there is a counter at
19
     row 31.
              Page 198, lines 1 to 16.
20
               MR. STANOCH: I think that was just an answer to a
21
     question. And if the question is coming out, the answer I
22
     think would come out, too.
23
               THE COURT: Yeah. It is just an answer. Okay.
24
               MS. LOCKARD: Yeah. So we'll withdraw it.
               THE COURT: So that's out as well.
25
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1
               So everything in row 31 is out.
               We're now to row 32.
 2
 3
               MR. STANOCH: Yes, sir. Page 200, line 12.
 4
               The objection is only to the beginning of this
 5
     question. At page 200, 12 through 14, if I'm reading
 6
     Ms. Lockard's objections correctly, then I'm fine beginning the
 7
     question at page 200:15. I just usually try not to do that
 8
     deliberately to cut things off, but if that's the objection,
 9
     I'm willing to agree to that.
10
               MS. LOCKARD: Okay. We'll accept that. So that was
11
     the only objection to that row.
12
               MR. STANOCH: Oh, okay.
13
               I am making the note.
14
               THE COURT: Okay. So row 32 is covered?
15
               MR. STANOCH: Yes, sir. We are trimming so that row
16
     32, page 200, lines 12 through 14 will be removed, but the
17
     remainder will remain in of that designation.
18
               THE COURT: Okay. Very well.
19
               MS. LOCKARD: So that takes us to row 33.
20
               THE COURT: All right. I know we do not have too
21
     much more to go, but I'd like to take a 15-minute break at this
22
     time.
            All right.
23
               MS. LOCKARD: Works for me.
24
               MR. STANOCH: Yes, sir.
25
               THE COURT: Okay.
                                  Thanks.
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1
               MR. STANOCH: Thank you.
 2
               (Recess was taken at 2:32 p.m. until 2:46 p.m.)
 3
               THE COURT: Okay. Are we all here?
               MR. STANOCH: Yes, Your Honor.
 4
 5
               THE COURT: Victoria, are you with us?
 6
               MS. LOCKARD:
                             I am. I am, Your Honor.
                                                       I'm here.
 7
               THE COURT: Okay. And, John, you're all set to go?
               THE COURT REPORTER: Yes. Thank you, Your Honor.
 8
 9
               THE COURT: So let me pull the spreadsheet back up.
10
               And what row are we up to now?
11
               MS. LOCKARD:
                             Thirty-four. No.
                                                Thirty-three.
12
               THE COURT: Thirty-three. That's what I thought.
13
               MS. LOCKARD:
                             But --
14
               THE COURT: This covers -- go ahead.
15
               MR. STANOCH: There's only 42 rows, Judge.
16
               THE COURT: I know. No.
                                         I knew we didn't have much
17
     longer to go, and I'm sorry, but I did have to take a call.
18
               MR. STANOCH:
                            No. Please, please.
19
               MS. LOCKARD: But I think the same issue that we're
20
     going to discuss applies to rows 33, 34, and 35.
21
               THE COURT: Okay.
22
               MS. LOCKARD: Okay. So this issue, this line of
23
     questioning relates to an email transaction that is between
24
     Dr. Nudelman, who's a toxicologist for Teva, he sits in Israel,
25
     and a woman who is at one of the Teva facilities in Japan.
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The Teva facility in Japan did not have anything to do with the valsartan that was produced for the U.S. market.

And so Judge Bumb has ruled that references and testimony and evidence related to Teva's other facilities that were producing valsartan for other markets around the world is not relevant to this case.

So my objection to these three rows relates to that because this is questioning of Mr. Binsol, Mr. Binsol, who is a 30(b)(6) witness who was identified to talk about testing and knowledge of nitrosamine levels for the drug at issue for the U.S. market. He did not — he was not identified and was not prepared to talk about issues related to every single Teva facility, just the U.S. market.

This line of questioning is highly irrelevant, prejudicial. And I'll tell you the reasons are because it's talking about the evaluation of a peak at a Japanese facility that did not produce the U.S. product or the product at issue. It was a peak that plaintiffs like the language where it says "unknown peak." It started off as an unknown peak, but it was identified as acetamide. It became a known peak. And acetamide is not at issue in formation of NDMA and NDEA in this case. It's a different impurity. And this is regarding what toxicological investigation was done. And so this witness is not here to talk about toxicological investigations. So it's just irrelevant.

I mean, the only thing it's probative of is to show that back during this time period, that there was an unknown peak that was initially called an unknown peak, it was determined to be acetamide, and it was sent to the global toxicologists to evaluate the toxicology for that acetamide impurity. Well, none of that has anything to do with unknown peaks determined to be nitrosamines in the U.S. product.

So we think all of those lines of questioning and this document are irrelevant, prejudicial. This witness lacks personal knowledge, it's outside the scope, and it should come out.

THE COURT: All right. David.

MR. STANOCH: Your Honor, this is the ZHP global -I'm sorry. Your Honor, this is a Teva global quality employee,
a 30(b)(6) on testing and testing methods. This is showing in
2016 Teva's knowledge about how it -- what it should do and the
steps it should take from a cGMP process and quality oversight
process; that it should be -- and has and does have global
processes that should be followed to properly identify and
characterize peaks.

That this one turned out to be something else, that's not the point. We're not trying to say oh, aha, Teva Japan called the NDMA first. This is showing what the Teva global process for quality is and should have been with respect to valsartan; that in this instance they were looking — testing a

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product, looked at a product, found something unknown and went through a process and knew how to do so in 2016. And we are comparing that to what did not happen with the valsartan, which we argued that they were not doing the same process, the same testing and proper characterization of the chemical composition of the valsartan they were purchasing.

And I asked him about processes in place at the time, about identifying unknown peaks in the testing that would be done and tie that back into in the questioning ZHP, in terms of at this time in 2016 was there a process to ensure conveyance of information from one Teva site to others that might be sourcing API from the same supplier, in this case ZHP. And go on about: Are you aware of the processes that were in place at Teva at the time for communicating with API suppliers about issues regarding the API being tested? And this was the way to establish that with this quality-and-testing witness.

MS. LOCKARD: But this witness was not identified to talk about global issues at Teva facilities in Japan or anywhere else other than the U.S., first of all; he was not.

And these questions are asking him questions about, well, what follow-up was done in this instance? Well, he doesn't know. He doesn't -- he doesn't oversee Teva's Japan facility. He wasn't identified to talk about those issues. Не wasn't prepared to talk about those issues. And so there's this line of questions which is, do you know what follow-up

occurred at Teva with respect to the identification of this unknown peak, and he says I do not. Well, that's prejudicial, because it makes it seem as if he's supposed to know when he's not. It's not his role. He doesn't have personal knowledge of that. And the whole ordeal of it — I mean, Judge Schneider specifically carved out issues related to what was going on at other Teva facilities and non-U.S. product in the discovery order. I mean, we didn't get into all of this in the discovery. We didn't have witnesses talk about it because it's not relevant.

So then to ask a witness in the 30(b)(6) deposition, well, what was the follow-up going on in Teva when they found an unknown peak, it's very misleading and prejudicial to suggest that he doesn't know or no one at Teva knows. But furthermore, it doesn't connect the dots to what's happening or what happened in the nitrosamine U.S. issue.

I mean, they're trying to say that, okay, well, they did identify the unknown peak because of acetamide and then they asked for a toxicology evaluation and that's somehow relevant to their argument here saying that we didn't do the right thing because nobody identified the unknown peak. I don't see how that connects at all.

I mean, if that's the case, then we should be able to bring out each and every single time that any Teva facility in the world identified an unknown peak, found out what it was,

did a proper toxicology examination. And, I mean, this is just getting into like, you know, 404 character evidence. Because then we're, all of a sudden, arguing about all these other times where we did the right thing.

So it just really -- we're going to have to take a lot of time to sort of explain this if we get into this. It just doesn't connect.

THE COURT: Yeah, I agree.

MR. STANOCH: May I?

THE COURT: I've heard -- go ahead, David.

MR. STANOCH: Just for the record, Your Honor, very briefly. Magistrate Judge -- we went over this the other week. I disagree with the characterization of Judge Schneider's discovery order. It allowed discovery regarding testing that could identify a nitrosamine-type issue, right? This is the same type of testing, right, that would do that. And this isn't just any old product that Teva was making anywhere in the world. This is about valsartan. This is about testing of valsartan and finding during the spectrometry testing an unknown peak and what happened. This is not saying some other, you know, some generic aspirin in South America, you know, you were looking for something else. This is exactly what we were allowed to get into.

Because, again, the ZHP email when it was talking about irbesartan, that's not excluded because it talks about

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irbesartan initially, right, because the same methods and issues should have led to the discovery of the NDMA in valsartan. And this is showing that here as well.
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MS. LOCKARD: Judge Schneider's ruling only applied to non-U.S., to the extent it related to the nitrosamine impurities. And this doesn't. It's a different impurity. It doesn't say anywhere in these documents anything about nitrosamine that he's been asking about.

MR. STANOCH: It --

MS. LOCKARD: So --

THE COURT: Yeah. I -- you know, I can understand how you can connect it, David, but I think it's not close enough to bring this into this trial, and we'll sustain the objection and strike the testimony that is covered by I guess it's rows 33, 34, and 35 of the spreadsheet.

MS. LOCKARD: Okay. So that takes us to page 210, row 36.

So we object on the basis of relevance, prejudice, 403 and hearsay.

So these -- this email is a -- or the document is a Mylan document, and it includes emails from someone at Matrix. So for the first objection we do believe that this is a hearsay document, notwithstanding, you know, whether it's contained within a business record, but we're talking about discussions with Matrix.

1.5

But on the larger issue, it is a document that's talking about Mylan product that is not the same product at issue here.

Mylan's product was a combination valsartan product. It was a valsartan amlodipine combination drug, and that is what these emails and these documents relate to. It does not relate to -- it goes to the Mylan issue. It does not relate to the valsartan -- the ZHP valsartan that's at issue in this case.

So it's talking about a discussion of a CE method under the European methodology rules. And we agree -- or we argue at least on this piece it also fails to connect the dots sufficient to allow Mr. Binsol to be asked about these documents.

THE COURT: All right. David.

MR. STANOCH: Thank you, Judge.

Number one, the document was produced by Mylan because Matrix is a subsidiary of Mylan. That's what that is. And it's emails between the Mylan/Matrix personnel and Teva personnel, right?

So Teva folks are sending and receiving this email and asking questions about it. That's number one.

Number two, this is a witness who is designated specifically on testing regarding valsartan. This is about the testing that was being done on a valsartan product, and it goes

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to the knowledge and capabilities and feasibility of using different testing methods to identify substances, including in this case the azide, which is part of the sodium azide that was part of the chemical reaction here that led to the formation of NDMA.

The email goes on and on and back and forth with Teva asking questions about the liquid chromatography and mass spectrometry, LCMS method, being more specific and sensitive to detect impurities at ppm, parts per million levels than HPLC.

And I'm sure Your Honor has heard plenty of times in the last month about the testing methods available and known at the time able to detect impurities in drug products. And this is Teva personnel talking in 2011 about using the more specific and sensitive LCMS method, the method that we say and that the FDA later said will detect these things to analyze impurities to the part per million level in a valsartan product.

So this is much more specific and tethered to the issues in this case than the arguments we've heard for the last email where we've heard that it was maybe about a different product or a different impurity or something else. focused on exactly the topics he was designated on, testing and testing methods, right? And it's talking about the very methods at issue in this case for testing impurities, and it's about valsartan.

> MS. LOCKARD: I just want to make sure I heard you

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1
     correctly.
 2
               You're not saying that Matrix is a part of Teva,
 3
     right?
 4
               MR. STANOCH: I said that Matrix was a subsidiary of
 5
     Mylan.
 6
               MS. LOCKARD:
                            Mylan. Okay. I wanted to make sure I
 7
     heard you correctly.
 8
               MR. STANOCH: It was the NDA -- or the ANDA holder.
 9
     Matrix is under Mylan.
10
               MS. LOCKARD: Right. Okay. I just want to make sure
11
     that was -- I may have misheard you.
12
               MR. STANOCH:
                            No; I said it.
13
               MS. LOCKARD: So the issue, though, is none of this
14
     testimony talks about the chromatograms. I mean, this is sort
15
     of -- it's not -- there's nothing much here that's relevant and
16
     compared to the prejudice that it presents and the confusion
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     that it presents. We're sort of introducing this Matrix
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     discussion. It doesn't -- this discussion about, you know, who
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     is this guy, you know, Gili Oshri, you know, there's nothing
20
     relevant in this discussion.
21
               I understand they want to introduce the document, I
22
     quess, because they like something that's in there. But
23
     there's nothing in this discussion that's relevant to this
24
     case.
25
               MR. STANOCH: Ten seconds, Your Honor.
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THE COURT: Yes. Yes, please. Because I am having trouble finding the relevance here.

MR. STANOCH: Sure, Your Honor.

Again, in the middle of these designations, right, at page 212, I asked the witness that -- we're talking about testing of valsartan and the methods to test valsartan that could find azide content. And I say: "Isn't it true that sodium azide content [sic] is a component of solvents, such as DMF?"

And he answers: "I know sodium azide is used as a quenching agent during the valsartan -- valsartan API manufacturing process," right.

So the witness is acknowledging, and I'm not surprised because he was designated on 22 or so topics regarding testing, right, that I'm asking him that in 2011 about what testing methods did Teva know existed to get the most specific levels of impurity testing, right. And he's saying, yes, GC-MS, right. And you can find sodium azide, which is one of the catalysts of the NDMA in the valsartan API at issue in this case.

And so when they say no one -- when they come in and say that nobody could find it, you wouldn't be able to -- we had to come up with a special test and we had to, you know, subcontract out a lab and we were using HPLC at the time and nobody would use GC-MS at the time, this is Teva saying years

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earlier, no, using GC-MS you can find things like the very catalyst that can lead to NDMA, and, in fact, we were doing that and quantifying it at very specific levels concerning impurities in valsartan product.
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THE COURT: Okay. Here's the problem I'm having right now, and maybe it's because I don't have the complete designation. The question and answer that you read starting at line 1 of page 212 is not part of what I reviewed because it wasn't designated as in dispute.

So when you read, "And in terms of azide content, isn't it true that sodium azide is a component of certain solvents, such as DMF," that's not in the designations that I have.

MS. LOCKARD: But we didn't object to that.

THE COURT: So it was --

MS. LOCKARD: Excuse me, Your Honor.

THE COURT: Okay. That's the problem.

MR. STANOCH: I'm sorry.

MS. LOCKARD: Yeah. The designation, just for clarity on the record, at page 212, line 1 to 7 which is the question, "In terms of azide content, isn't it true that sodium azide is a component of certain solvents, such as DMF," and he answers, we did not object, because in fairness to Mr. Stanoch's point and yours, that is a fact, I guess, that you're asking him about and he answers it.

But my problem is all the back-and-forth about this hearsay email with Matrix and Mylan, which I don't think that he needs that. I think it's hearsay, and he doesn't need that in order to get to the underlying fact of if this is -- azide is a component of DMF.

And then there's nothing in the other designations or this one about showing any knowledge that Teva was aware of its knowledge of testing methods to pick up NDMA.

So that is an argument they want to make, but that's not in the testimony that's being disputed.

MR. STANOCH: Your Honor.

THE COURT: Go ahead.

MR. STANOCH: You know, given that, if part of this is back-and-forth questioning about Matrix, Mylan, maybe I can limit this to the designation introducing the document, right, just simply this is an email, it is from whatever date, and then -- I'm seeing if I could just withdraw the rest, if Your Honor would give me a moment.

THE COURT: Yeah. And I tell you to look specifically at page 212, line 15 to 213, line 8.

MR. STANOCH: I will withdraw 212:15 to 213, line 8 right now.

THE COURT: All right.

MR. STANOCH: So then I would only -- I would on the one before that, I'm happy just to introduce the document at

210:11 through 16, and then on 211, I would jump to 211:12. It's just basically -- so it's saying this is the document. It's talking about the determination of azide content in valsartan. He says, hold on. I give him time. He says yes. That way I don't get into Matrix, Mylan and a lot of what I'm hearing from Ms. Lockard.

MS. LOCKARD: But there's no basis for the document to be introduced through this witness when -- I mean, it's not his document, and it's a hearsay document. And to introduce the document and then just ask the question, well, azide is a component of sodium azide, isn't it, yes, and then move on, that just doesn't follow. I don't think he needs that document with this witness.

If there's another witness he can introduce it with, you know, to, you know, provide some context for what it is and authenticate it in a sense, but this is something that came from Mylan's production, not ours. So I would not agree to that proposal.

MR. STANOCH: And, Your Honor, the point here is not just the testimony of "sodium azide is a component of certain solvents like DMF," sure, right, but completely divorced from this, you know, part of this is that it was a conversation that Teva was having in 2011, and not to have in there that that conversation was happening in 2011. I think that swings too far the back way, especially I'm trying to address all these

other issues with the email and the folks involved.

And, again, remember, this is four years ago before we knew what the last trial was going to be.

THE COURT: I understand.

MR. STANOCH: So in hindsight, I wish I had done this a little differently, but it's 20/20 in that regard.

THE COURT: Yeah.

MS. LOCKARD: I just don't see that's appropriate under the evidentiary rules to just introduce a document through a witness who has no information about the document, you don't ask him any questions about it, and then you're going to use that to try to authenticate it to get it into evidence. I don't — that doesn't flow.

MR. STANOCH: Well, that's what I'm taking out, because I -- I asked him about the email and who it's with and it's with Gili Oshri, O-S-H-R-I, you know, right, and who the people are and they're at Teva Israel. And then I talk about their Teva Israel email addresses, et cetera. I'm taking all that out because I'm hearing that it's superfluous, but then --

MS. LOCKARD: But he's just reading what -- who's on the email address. He's not on the -- he wasn't sent this.

MR. STANOCH: He's a 30(b)(6) on testing methods for Mylan, by the way, and ZHP. And this is testing methods being used for valsartan with Mylan.

MS. LOCKARD: I mean, but Mylan isn't in this trial,

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1
     so I still think it's not relevant.
 2
               (Pause.)
 3
               THE COURT: Yeah. I've gone back over this. I'm
 4
     looking at this line of testimony again, and I'm really
 5
     struggling with it, David.
 6
               MR. STANOCH: I hear Your Honor saying you're
 7
     sustaining the objection.
                                I'11 --
 8
               THE COURT: I sustain the objection.
 9
               MR. STANOCH: I understand Your Honor's ruling.
10
     I'm...
11
               THE COURT: Yeah. It's sustained.
12
               MR. STANOCH: And that would apply to row 36, which
13
     is page 210. I had already withdrawn row 37. I think that's
14
     right.
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               THE COURT: Yeah. I think that's right.
               MS. LOCKARD: And row 38.
16
17
               MR. STANOCH: That's a different document.
18
               THE COURT: Yes. It's a different document.
19
               MS. LOCKARD: Okay. I see. All right. Let's move
20
     to that.
21
               Okay. All right. So this is a different document,
22
     similar objection as to relevance, prejudice, and confusion.
23
     This is another one where, you know, we would say they haven't
24
     properly connected the dots. And in the email he's being asked
25
     about the Bulgarian Teva site, which is not at issue in this
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case, and there's a discussion asking — they have an impurity that they've identified, and it will — the shorthand is MBS and EBS. It's not a nitrosamine. It is an impurity that was detected in the amlodipine valsartan, which is not the drug at issue. That's the combination product. That's not the drug here. And there is a discussion about asking for outside labs or capability for testing the MBS and the EBS.

So from our perspective, it offers no probative value because it's not the drug at issue. It's not the facility at issue, and it's not the impurity at issue.

And I know that the subject line itself says

"genotoxic impurity in amlodipine valsartan," which is very

attractive for plaintiffs' case, to suggest, oh, well, there

are all these impurities in valsartan. But it is really

misleading to put before the jury testimony about this with

this witness, because it's not the right product, it's not the

right facility, and it's not the right impurity. And so

discussions about, well, is there a lab or capability to test

this other thing, that is far afield and not connected

sufficiently with the dots.

THE COURT: David.

MR. STANOCH: Your Honor, this is the facility at which Teva conducted testing of the valsartan API and its finished dose after June 2018, right? And so this is the very facility it sent valsartan finished dose or valsartan API from

ZHP to be tested, right?

And this is an email just a few months before that, right, in April, in May of 2018 in which those personnel, the same personnel who are in just a few months going to test the valsartan at issue here are talking about the technology and ability and feasibility and methods for testing a valsartan product. And it's talking about what can be done, what cannot be done, and also more importantly, there's discussion here about whether they should require additional genotoxic testing from suppliers of valsartan, of a valsartan product.

So I think it's relevant. I think it's squarely within the topics of this testing-and-quality witness, and it goes — he's the designee on testing. And it obviously goes to knowledge both predating the recalls as well as the feasibility of asking suppliers for additional information regarding testing for genotoxic impurities.

It doesn't have to -- again, it doesn't have to be the exact NDMA impurity, right? That's not what this is. But this is the very facility that's doing -- that will do the testing two months later and what they're saying about genotoxic impurities and the methods and if it's feasible or not to test for it, all of that is probative and within the scope of the 30(b)(6).

THE COURT: I know he was a 30(b)(6) deponent, but I'm having trouble with the testimony that he gave. You have

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him scroll through the email, but then you ask him: "You weren't involved in the effort here regarding the potential genotoxic impurities in valsartan amlodipine finished product in April of 2018, right?
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"No, I wasn't."

MR. STANOCH: Right.

THE COURT: Which predates your arrival.

MR. STANOCH: That's right. He --

THE COURT: And then you asked him about the outcomes, and he says I don't know the specifics or actually the outcome.

MR. STANOCH: Yes, Your Honor. And I think in a 30(b)(6) context, just because he came on to Teva after the recalls, right, everything is outside his personal knowledge, right? Because he wasn't there, right? That's number one. I didn't make him the 30(b)(6); they did. They said here's our guy to talk about testing, you know, 22 or so testing items, right? So I'm asking him what he, he knows, or Teva knows, frankly, on testing, and he doesn't — and he doesn't know, and doesn't know what the outcome is. And that fact alone I think is probative and relevant in terms of — go ahead. Go ahead, Ms. Lockard.

MS. LOCKARD: But he was — he was identified as a 30(b)(6) on testing issues related to nitrosamines. This is a testing question and email about testing of totally different

impurities, MBS and EBS.

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So we properly prepared him to talk about testing capabilities and what was available both equipment-wise and validated test methodologies for nitrosamines. So he was prepared on that. But he wasn't prepared on these, you know, issues that are totally extraneous about some email about testing for something totally different.

MR. STANOCH: And it also talks about, Your Honor, about the ICH M7 guidelines and what the testing that requires generally for genotoxic impurities, not just about the one specific one in this email. And it talks about the testing methods that are appropriate to analyze genotoxic impurities, right, the testing methods that they say two months earlier they should use for genotoxic impurities.

MS. LOCKARD: That's not in the testimony.

THE COURT: Yeah. I didn't see it in the testimony.

It might be in the email. I don't know. I don't have the email.

I'm going to sustain the objection covered by row 38.

And row 39, I think, as well.

So are we at row 40?

MS. LOCKARD: We are at row 40. And this row kind of continues --

MR. STANOCH: I'm sorry to cut you off, Ms. Lockard.

25 It's just row 39 at page 218, Your Honor?

THE COURT: Yeah, 218.

MR. STANOCH: I shift gears and I'm asking him about his fluency and what he speaks.

THE COURT: Oh, yes, yes.

MR. STANOCH: Right. This is just setting up the foundation for the next question, right, because the next question is the final two rows. It's an email in part in Hebrew, right?

THE COURT: Right.

MR. STANOCH: So I was asking him really his own facilities with other languages and especially Hebrew because it's going to come up. And, you know, Ms. Lockard likes to say what's attractive or not or sexy for a plaintiff's case, but you know, the fact that he says he runs something through, you know, Google translation if he has to, if that's how Teva's quality 30(b)(6) on testing designee is handling dealing with quality issues when talking with his Israeli colleagues, I think that's something the jury can hear. I don't mean to be flip about it. I think it's both foundational for the next — the final two rows because the email is in Hebrew. And if he's saying, you know what, if I see some other language, I just use Google, you know, I think a jury can infer what they like from that.

THE COURT: Yeah. And I misspoke. You know, we were covering row 38.

MR. STANOCH: I understand.

THE COURT: I had not gotten to row 39.

MS. LOCKARD: Yeah. And I agree the language issue is a different -- a new issue.

But he hasn't -- if there was a question that said, oh, this document is in Hebrew, did you translate it via Google and he said yes, that's different. He doesn't say that. He's asked, Do you speak French? Yes. Do you speak Hebrew? I don't. Well, what do you -- you know, do you ever get emails from colleagues in Hebrew? And he says not directly addressed to me in Hebrew. There may be trailing emails that, you know, someone forwards to me.

So on one hand as to row 39, the answer isn't even included there, where he's basically explaining no, if it's sent to me, it's not in Hebrew usually, it's only if I'm just copied.

But overall, it's not -- there's no correlation because there's no document in Hebrew where he said, oh, I couldn't read this in Hebrew so I had to Google Translate it. It's kind of drawing -- it's a big -- a big analytical leap to suggest that oh, well, then any document that he was copied on in Hebrew he had to Google Translate it. So I just think it's a diversion and it's not relevant.

MR. STANOCH: It's a global company, Your Honor.

There's lots of emails you're seeing in lots of languages. I

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was just trying to set up a foundation when we get to documents
in other languages, because it's going to occur -- it occurred
to me and it might occur to other laypeople, oh, my gosh, how
are you doing with these complex, technical quality issues when
you have people speaking dozens of different languages around
the world, and he explains what that is. He talks about what
happens, what he does, about official translations. He answers
whether there's a policy about it. You know, I'm not going to
belabor it.
          THE COURT: Yeah.
          MR. STANOCH: But I don't -- I don't really see what
the --
          THE COURT: I'll overrule the objection to the lines
of questioning on page 218 starting at line 18 and continuing
to 219 at line 7.
          So all of that comes in.
          MS. LOCKARD: So understood, Your Honor. So we would
ask that -- oh, okay. So did I hear you say you would include
the answer at 219, 4 to 7?
          THE COURT: Yeah. That has to come in.
          MS. LOCKARD:
                        Okay.
          MR. STANOCH:
                      No objection.
          MS. LOCKARD:
                        Okay.
          And then I think that would apply to the next row,
219:22 to 228.
               That's where he really brings in the Google
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1
     Translate.
 2
               THE COURT: Yeah. It would apply to that as well.
 3
               That takes us through line 9 of -- whoops. I'm lost
 4
     now.
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               MR. STANOCH: I think lines 41 and 42, Judge.
 6
               THE COURT: Yeah.
 7
               MS. LOCKARD: Rows, yeah.
 8
               THE COURT: Rows 41 and 42 of the spreadsheet.
 9
               MR. STANOCH: Yes, sir.
10
               THE COURT: And row 41 deals with the testimony
11
     starting at line 12 of page 221 and going to 224, line 9.
12
               MS. LOCKARD: Okay. Let me get reoriented here.
13
               THE COURT: Yep.
14
               (Pause.)
15
               MS. LOCKARD: Give me just one second, and I might be
16
     able to resolve it.
17
               THE COURT: Uh-huh.
                                    Okay.
18
               MR. STANOCH: I would give her two seconds then, Your
19
     Honor.
20
               MS. LOCKARD: Yeah. I'm trying to pull up the
21
     transcript, because I think this was -- this was an issue that
22
     was ruled upon by Judge Bumb related to the Bogoslavski email.
23
               (Court reporter clarification.)
24
               MS. LOCKARD: I'm sorry. Bogoslavski. It's spelled
25
     B-O-G-O-S-L-A-V-S-K-I.
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               MR. STANOCH: I'm not holding you to that, Counsel.
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     I just didn't see any reference to that in the spreadsheet,
 3
     so...
 4
               MS. LOCKARD: I know. I thought I included -- that's
 5
     why I'm taking so long. I thought I had made a note on the
     spreadsheet, but maybe when I put it to you I didn't include
 6
 7
     that reference to the MIL.
 8
               MR. STANOCH: Again, I'm not seeking to preclude you.
 9
     I understand.
10
               MS. LOCKARD: Let me say this: If this was addressed
11
     by Judge -- let me pull up -- I'm having a problem with my
12
     equipment pulling up that.
13
               If it was ruled out by Judge Bumb and if we believe
14
     that it was, then I would continue my objection. If it wasn't,
15
     then I think I can withdraw the objection here.
16
               MR. STANOCH: I think she said, again, I'm not
17
     putting words in your mouth, if this was up, I thought she said
18
     something along the lines of this was a jury question. But,
     again, I'm -- because it's a 2017 email, and I think that's
19
20
     what I recall from July.
21
               MS. LOCKARD: Okay. Let's do this, I'm emailing
22
     somebody whose name will remain nameless, but he's on this call
23
     right now saying "pull this up for me."
24
               Let's -- let's -- can we just agree that we'll do
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what Judge Bumb said. And if there's any dispute, we have to

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1
     talk about the one other remaining issue.
 2
               THE COURT: Correct.
 3
               MS. LOCKARD: And if this needs to be addressed by
     Judge Vanaskie, then we can bring that up again.
 4
 5
               But I want to take a look at the Judge's ruling to
 6
     make sure because -- if that's okay with you, Judge.
 7
               THE COURT: Yeah.
 8
               MS. LOCKARD: And then we can just report on our
 9
     agreement. And then that would apply to the last two.
10
               THE COURT: That's fine with me.
11
               So we'll report back by Thursday. Now on row 42.
12
               MR. STANOCH: Same. Same thing, I think, Judge.
13
               THE COURT: Right? Okay.
14
               MR. STANOCH: I think so. If Ms. Lockard agrees.
15
               MS. LOCKARD: Yes. 41 and 42. Yeah. Okav.
                                                             So
16
     we'll do that. So that resolves everything except for those
17
     two remaining issues.
18
               THE COURT: Yeah. I've got still at issue rows 5 and
19
     6 and rows 41 and 42.
20
               MR. STANOCH: I agree.
21
               THE COURT: All right.
22
               MS. LOCKARD: Yes. I agree.
23
               THE COURT: Okay. Great. Is that it for today then?
24
               MS. LOCKARD: I think that's it for today, unless you
25
     had any further thoughts on the pretrial order. I believe the
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1
     parties, we're about to do a meet-and-confer, plaintiffs and
 2
     defendants, on the pretrial order at 3:30.
 3
               THE COURT: Okay.
               MS. LOCKARD: So if there's anything you want to
 4
 5
     impart on us, we can share with the rest of the group.
 6
               THE COURT: I don't have anything to impart on you at
 7
     this time.
 8
               MS. LOCKARD:
                            Okay.
 9
               THE COURT: And I do anticipate being there Thursday
     for the case management conference being conducted by Judge
10
11
     Bumb. But I don't have anything. But if I have anything by
12
     then, I'll certainly let you know.
13
               MS. LOCKARD: Okay. That sounds good. I just wanted
14
     to make sure.
15
               THE COURT: All right.
16
               MS. LOCKARD: Okay. Appreciate it. Thank you, Your
17
     Honor.
18
               THE COURT: Thank you all very much. Yes. Bye-bye.
19
               MS. LOCKARD: Thank you.
20
               MR. STANOCH: Thank you, Judge.
21
               THE COURT: Thanks, John.
22
               THE COURT REPORTER: Yes, Your Honor. Thank you.
23
               (Proceedings concluded at 3:31 p.m.)
24
              FEDERAL OFFICIAL COURT REPORTER'S CERTIFICATE
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I certify that the foregoing is a correct transcript
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     from the record of proceedings in the above-entitled matter.
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     /S/John J. Kurz, RDR-RMR-CRR-CRC
                                                   October 9, 2024
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     Court Reporter/Transcriber
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MR. STANOCH: [145]	58/16	404 [1] 64/2	acidic [1] 21/5	27/22 55/24 59/14 64/10
MS. LOCKARD: [148]	20005 [1] 2/11	41 [9] 5/16 10/19 10/20	acknowledges [2] 24/20	71/12 77/21 77/21
THE COURT	20016 [1] 2/3	10/22 82/5 82/8 82/10	34/16	aided [1] 1/24
REPORTER: [4] 28/10	200:15 [1] 58/7	84/15 84/19	acknowledging [4] 34/10	ALEXANDRE [1] 2/19
29/7 59/8 85/22	2011 [7] 24/12 48/21	42 [6] 59/15 82/5 82/8	34/14 45/7 69/13	all [99]
THE COURT: [177]	49/10 67/13 69/15 72/23	84/11 84/15 84/19	acknowledgment [1]	allow [6] 25/12 36/5
	72/24	42-128 [1] 2/6	23/21	36/12 50/7 55/8 66/13
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10 [2] 30/10 31/21	210 [2] 65/16 74/13	576-7094 [1] 1/22	added [1] 29/17	19/4 20/7 29/12 31/3
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10022 [1] 2/20	211:12 [1] 72/1	6	address [7] 4/14 5/12	although [1] 33/13
100:16 [1] 53/20	212 [4] 69/5 70/8 70/20		13/10 16/12 26/2 72/25	am [10] 4/12 6/18 7/6 9/3
100:8 [3] 51/20 51/23	71/20	601 [1] 2/19	73/21	9/3 25/25 58/13 59/6 59/6
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